



The Pharmacist Activist

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Editorial

Walgreens Challenges CVS in the Race to the Bottom – But No Individuals are Accountable!

The Drug Enforcement Administration (DEA) news release dated June 11 has the title, “Walgreens Agrees to Pay a Record Settlement of \$80 Million for Civil Penalties under the Controlled Substances Act.” The previous record settlement was \$75 million that CVS agreed to pay in late 2010 because of its illegal conduct in selling pseudoephedrine to criminals who made methamphetamine. The Walgreens settlement quickly became national news with the Wall Street Journal, USA Today, the New York Times, and many others providing coverage. The following are among the specific statements included in the DEA news release:

The agreement resolves “the DEA’s administrative actions and the United States Attorney’s Office’s civil penalty investigation regarding the Walgreens Jupiter Distribution Center and six Walgreens retail pharmacies in Florida. The settlement further resolves similar open civil investigations in the District of Columbia, Eastern District of Michigan, and Eastern District of New York, as well as civil investigations by DEA field offices nationwide...”

“The Registrants negligently allowed controlled substances listed in Schedules II-V of the Act, such as oxycodone and other prescription pain killers, to be diverted for abuse and illegal black market sales.”

“This settlement sends out a clear message that all DEA registrants will be held accountable when they violate the law and threaten public health.”

“Walgreens alleged failure to sufficiently report suspicious orders was a systematic practice that resulted in at least tens of thousands of violations...”

“The six retail pharmacies...filled customer prescriptions that they knew or should have known were not for legitimate medical use.”

“These (six) retail pharmacies and others elsewhere in the United States failed to properly identify and mark, as required by DEA regulations, hardcopy controlled substance prescriptions that were outsourced to a ‘central fill’ pharmacy for filling...DEA could not accurately determine which prescriptions were filled from the retail pharmacies’ own drug supplies and which prescriptions were filled by a ‘central fill.’ Consequently, DEA could not determine the accuracy of the retail pharmacies’ drug records. The DEA’s administrative actions demonstrated millions of violations of this type.”

“In addition to the \$80 million civil penalty for the above violations, the settlement revokes the Registrants’ (Walgreens Jupiter

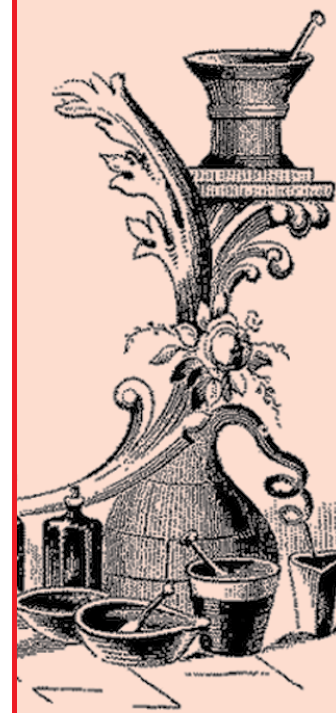
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Distribution Center and six retail pharmacies) ability to distribute or dispense controlled substances listed in Schedules II-V for two years, ending in 2014.”

“Walgreens has agreed to create a Department of Pharmaceutical Integrity to ensure regulatory compliance and prevent the diversion of controlled substances. Walgreens has also agreed to enhance its training and compliance programs, and to no longer monetarily or otherwise compensate its pharmacists based on the volume of prescriptions filled.”

Walgreens’ statement

Walgreens’ President of pharmacy, health, and wellness issued a statement concerning the DEA agreement that includes the following statements:

“As the largest pharmacy chain in the U.S., we are fully committed to doing our part to prevent prescription drug abuse.”

“The agreement resolves all pending litigation and requires Walgreens to surrender its DEA registrations at only six of its more than 800 Florida pharmacies until May 2014 and at its Jupiter distribution center until September 2014.”

“The company expects the total impact of the agreement and other associated costs to be 4 to 6 cents per share in its third fiscal quarter.”

The Walgreens’ statement does not include any expression of apology or regret for the circumstances for which it was responsible, or that there must have been victims and deaths resulting from its actions. Indeed, certain of its words and statements tend to minimize what has occurred. For example, the word “only” is used to refer to its six pharmacies that surrendered DEA registrations. I would contend that one pharmacy should be considered too many for this action to be necessary. The question should also be asked as to what number of pharmacies would have had to be involved for Walgreens to no longer consider the word “only” to be appropriate.

Also, it is almost amusing that what most would consider to be a huge settlement of \$80 million can be so diminished in apparent value that it can be equated to only a few pennies a share.

Were there victims?

The DEA news release includes statements such as: “Every day individuals die from prescription drug overdoses.” and

“Prescription drug overdose deaths exceeded motor vehicle deaths and deaths from illegal street drugs, such as cocaine, heroin, and amphetamines, in 2009.” However, there is no mention of deaths that certainly had to have resulted from violations in such numbers and importance to warrant a settlement with Walgreens in the amount of \$80 million. Were there no investigations of the outcomes of the actions and negligence that resulted in oxycodone and other pain killers being “diverted for abuse and illegal black market sales?” Were such investigations preempted by agreement to an \$80 million settlement, or are investigations continuing?

Such an investigation might initially focus on just one of the six pharmacies and the patients (or a random sampling of the patients) who obtained prescriptions for oxycodone that were associated with violations. The pharmacy would have the names and addresses of those receiving prescriptions for oxycodone, and those conducting the investigation would contact them. It is my expectation that it would be learned that some of these individuals died from prescription drug overdoses. How many?

No accountability

I find it remarkable that violations and other illegal/inappropriate actions can occur in such numbers and be of such importance to warrant a settlement of \$80 million, but no individuals are identified as being at fault. There must be pharmacists, managers, and executives who are at fault and should be held accountable. The DEA seems satisfied by obtaining a “record” settlement of \$80 million. Walgreens has trivialized the settlement by equating it to a few cents per share and gives no indication that the individuals responsible for this debacle are being held accountable. If DEA’s investigation of illegal actions/violations ends with the settlement, what are the appropriate roles for the police and state Board of Pharmacy?

Executives and managers of chain pharmacies have the responsibilities for establishing policies, staffing levels, and other procedures pertinent to the operation of the pharmacies, as well as the compensation and incentives/rewards for pharmacists and other employees. Although the executives and managers must share the responsibility and accountability with respect to the operation of a pharmacy, it is pharmacists who have the primary responsibility and accountability for decisions and actions in dispensing prescriptions. It is pharmacists who have the primary responsibilities for the quality and accuracy of the medications and services provided to patients. And it is also pharmacists who are at greatest risk of losing their reputation,

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New Drug Review

New Drug Comparison Rating (NDCR) = 3

(no or minor advantages/disadvantages) in a scale of 1 to 5 with 5 being the highest rating

Alogliptin benzoate (Nesina – Takeda)

Antidiabetic Agent

Indications:

Adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

Comparable drugs:

Sitagliptin (Januvia), saxagliptin (Onglyza), linagliptin (Tradjenta).

Advantages:

- Less likely to interact with other drugs (compared with linagliptin and saxagliptin);
- Available in a combination formulation with pioglitazone.

Disadvantages:

- Has not been directly compared with other dipeptidyl peptidase-4 (DPP-4) inhibitors in clinical studies;
- Dosage must be adjusted in patients with moderate or severe renal impairment (compared with linagliptin).

Most important risks/adverse events:

Pancreatitis (treatment should be promptly discontinued if pancreatitis is suspected); hypersensitivity reactions; hepatic effects; risk of hypoglycemia when used in combination with insulin or an insulin secretagogue (e.g., sulfonylureas).

Most common adverse events:

Nasopharyngitis (4%), headache (4%), upper respiratory tract infection (4%).

Usual dosage:

25 mg once a day; in patients with moderate renal impairment – 12.5 mg once a day; in patients with severe renal impairment or end-stage renal disease – 6.25 mg once a day.

Products:

Film-coated tablets – 6.25 mg, 12.5 mg, 25 mg; combination formulation with metformin (Kazano); combination formulation with pioglitazone (Oseni).

Comments:

Alogliptin is the fourth dipeptidyl peptidase-4 (DPP-4) inhibitor, joining sitagliptin, saxagliptin, and linagliptin. By inhibiting the inactivation of incretins, it increases and prolongs their activity in increasing insulin biosynthesis and secretion. The effectiveness of alogliptin was demonstrated in placebo-controlled studies in which it was used as monotherapy, and in combination with metformin, glyburide, pioglitazone (either alone or in combination with metformin or a sulfonylurea), and insulin (either alone or in combination with metformin). It reduced hemoglobin A1C (HbA1C) by up to 0.6% compared with placebo, and also reduced fasting plasma glucose.

The absolute bioavailability of alogliptin is approximately 100%. It is metabolized to only a limited extent and approximately 75% of a dose is eliminated in the urine, primarily as unchanged drug. The dosage should be reduced in patients with moderate or severe renal impairment.

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job, license, and assets when errors, illegal actions, and other inappropriate situations occur when they are “in charge.”

In a recent discussion about these issues with an experienced chain pharmacist whom I hold in very high regard, he made the following observation. “If I followed up (e.g., with a telephone call) on every prescription for which there was a computer alert or other question or suspicion regarding the prescription, the line of patients waiting for prescriptions would extend out the front door. I do not have enough help and time to follow up.” I know that this observation also represents the experience of thousands of other pharmacists. However, we must not compromise the standards and responsibilities that we recognize to be important in protecting the safety of those whom we serve, as well as those whom we must decline to serve because of concerns regarding the validity of a prescription or problem of abuse.

The DEA is not without fault

The DEA has very important and difficult responsibilities. However, questions exist regarding certain of their actions and tactics. I am aware of situations in which pharmacists have lost their license, pharmacy, and freedom (i.e., jail terms) because they violated provisions of the Controlled Substances Act. I am not defending what they have done but their consequences have been severe. In sharp contrast, the settlement with Walgreens gives the impression that the DEA is so satisfied with the “record” settlement of \$80 million that they do not care whether any individuals should be considered accountable. I am not advocating jail terms for more pharmacists but rather I contend that, under the banner of “justice”, the DEA has taken actions that have resulted in injustice for some pharmacists because of the vast differences among cases in the extent to which they made individuals accountable.

Can there be a silver lining?

Toward the end of the DEA press release, there is a statement that could easily escape attention. As part of the settlement agreement, Walgreens agreed to no longer monetarily or

otherwise compensate its pharmacists based on the volume of prescriptions filled. I consider this to be the most important part of the settlement that also has implications for other chain pharmacies. This provision pertains to the time available for pharmacists to fulfill their responsibilities to patients and, therefore, to the level of pharmacist and technician staffing. Whether working at Walgreens or another pharmacy, pharmacists must take the time that is necessary to assess the appropriateness of prescriptions, accurately prepare the prescriptions, and provide the counseling and services that are necessary for patients to use the medications as effectively and safely as possible. I am not naïve enough to think that Walgreens will initiate substantial changes to comply with this provision of the settlement agreement but I also feel that they will have to be very reluctant to challenge a pharmacist who insists that more time and help are needed to assure the safety of their patients and also to protect the company against future litigation and settlements.

What if?

Walgreens is paying \$80 million and CVS recently paid \$75 in settlements regarding their violations and other inappropriate actions. These companies must make a commitment to do the right things rather than engage in the wrong things. I was speaking recently with an attorney who has considerable experience in representing patients who were suing pharmacies because of prescription errors and/or negligence. He voiced the opinion that the large chains will not change and do the right things until the number of lawsuits in which punitive damages (not covered by insurance) are awarded reach a number at which the financial impact will force them to make changes.

But what if, instead of paying tens of millions of dollars into settlements, Walgreens and CVS would commit funding at a similar level to expand professional services to patients and to strengthen the professional roles of their pharmacists? Their customers, their pharmacists and other employees, the companies themselves, and the profession of pharmacy would all benefit.

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